Delaware Healthcare Association

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The Honorable Trinidad Navarro
Attn: Regulatory Specialist
Delaware Department of Insurance
1351 West North Street, Suite 101
Dover, DE 19904
SUBMITTED BY EMAIL: DOI_Legal@delaware.gov

Re: Proposed Regulation 1322 for Mandatory Minimum Payment Innovations in Health Insurance

Dear Commissioner Navarro:

The Delaware Healthcare Association (DHA) appreciates the opportunity to comment in response to Proposed Regulation 1322 for Mandatory Minimum Payment Innovations in Health Insurance (the "Regulation"). We are writing to express our strong concerns with the Proposed Regulation that goes far beyond the intent and scope of SS1 to SB 120. We urge the Delaware Department of Insurance and the Office of Value Based Health Care Delivery (collectively, the "Department") to withdraw and re-propose the Regulation. We would appreciate the opportunity to work with the Department on a re-proposed regulation that more closely aligns with SS1 to SB 120.

While the intent of SS1 of SB 120 is to strengthen primary care in the state of Delaware, it is worth noting that the implementation of the Act thus far has *not* focused on primary care, but instead on provisions that will negatively impact Delaware hospitals and further compromise our ability to provide access to high quality care, particularly as we are now in the third year of pandemic crisis management, driving our staffing and capacity to crisis levels and forcing many Delaware health systems to adopt Crisis Standards of Care for the first time in a century. The Proposed Regulation is a vast overreach that seeks to upend payer-provider negotiated contracts and micromanage the contracting of hospitals over which the Department of Insurance has no regulatory authority. Even more concerning is the fact that the Department has casually disregarded the carefully considered language that the Delaware General Assembly adopted after considerable negotiations, debate and input from stakeholders.

Specifically, DHA has the following concerns with the Proposed Regulation as currently written:

1. **Core Consumer Price Index (CPI) with a three-year lookback methodology, as contemplated in § 7.3 of the Proposed Regulation, is inconsistent with the plain language of the statute and will be grossly inadequate in the current inflationary environment.** Sections 7.0-7.2 of the Proposed Regulation, *excerpted below*, track the statutory language of SS1 for SB120 (the "Legislation"), but the Department has

added a new provision in Section 7.3, authorizing the Commissioner to annually determine the Core CPI percentage increase based on a three-year lookback provision that does not appear and is not otherwise contemplated in the statute.

> *7.0 No carrier shall submit a rate filing for a health benefit plan that includes aggregate unit price growth for nonprofessional services that exceeds the following:*
>
> *7.1.1 In 2022, the greater of 3 percent or Core CPI plus 1 percent.*
>
> *7.1.2 In 2023, the greater of 2.5 percent or Core CPI plus 1 percent.*
>
> *7.1.3 In 2024, 2025, and 2026, the greater of 2 percent or Core CPI plus 1 percent.*
>
> *7.2 Each carrier rate filing for a health benefit plan for each plan year shall be based on fee schedules and reimbursement structures that include increases that are no greater than the limits set forth in subsection 7.1 of this regulation.*
>
> *7.3 The Commissioner shall annually determine the Core CPI percentage increase based on an average of the previous three years United States Department of Labor data and shall communicate this determination annually to carriers by Bulletin or other form of notice.*

The General Assembly intentionally selected Core CPI, not CPI, as the inflationary index to minimize year-over-year volatility that the broader CPI metric may otherwise reflect in a year-over-year inflationary index. The General Assembly was deliberate and thoughtful in the selection of the methodology and in the specific years set forth in the three-year implementation timeline. It is not appropriate, and not consistent with the intent of the General Assembly, for the Department to utilize the three-year smoothing methodology contemplated in the Proposed Regulation, and the Proposed Regulation appears to be designed to ignore the fact that both Core CPI and regular CPI reached historically high levels in 2021 (with CPI reaching near 7%, and Core CPI close to 5%, as of December 2021). [i]

Moreover, adding a three-year lookback in the current pandemic environment is particularly inappropriate when Delaware hospitals and health systems (along with their counterparts nationwide) continue to experience unprecedented staffing, supply chain and other expenses that have escalated in the current Omicron variant surge. Healthcare staffing costs alone will make it difficult to stay within the Core CPI inflationary index as the statute is currently drafted. Amending the statute by the Proposed Regulation to add on a three-year lookback provision will make it even more difficult for health systems and hospitals to plan for 2023 and beyond. This challenge was underscored in a recent analysis by a leading healthcare industry analyst:

> "As the delta variant pushes COVID-19 caseloads to all-time highs, hospitals and health systems across the country are paying $24B more per year for qualified clinical labor than they did pre-pandemic, according to a new PINC AI analysis. The analysis found that **clinical**

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labor costs are up by an average of 8 percent per patient day when compared to a pre-pandemic baseline period in 2019. For the average 500 bed facility, this translates to $17M in additional annual labor expenses since the pandemic began."[ii]

2. **The definition of "primary care," including services within the scope of the mandatory percentage targets, is a substantive and material regulatory requirement, not mere technical guidance. As such, it must be defined in regulation, not deferred to a future insurance bulletin.**

   The Proposed Regulation defines "Primary care services" and "primary care" as follows:

   > *"Primary care services" or "primary care" means the provision of integrated, accessible health care services by primary care providers and their health care teams who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. The care is person-centered, team-based, community-aligned, and designed to achieve better health, better care, and lower costs. Services qualifying as primary care services or primary care will be determined by the Department and changes will be communicated annually to carriers by annual notice.*

   SS1 for SB120 explicitly states that "'primary care' means as defined by the Department in **regulations** promulgated under this Section. (emphasis added)" The General Assembly clearly directed the Department to promulgate a regulation containing the details of this critically important definition, which is material to the Department's oversight and decision-making process for enforcing this statute. A broad definition of "primary care" with a promise of a future communication to carriers (as opposed to a public notice and comment in a proposed administrative rulemaking) is not sufficient.

   Delaware Courts have intervened in similar instances of an administrative agency over-stepping its statutory authority by side-stepping the Administrative Procedures Act's (APA) notice and comment process and burying important substantive guidance in so-called "technical guidance documents." *See, e.g.*, *Baker v. Delaware Dep't of Nat. Res. & Env't Control*, No. CV S13C-08-026, 2015 WL 5971784, at *15 (Del. Super. Ct. Oct. 7, 2015), aff'd, 137 A.3d 122 (Del. 2016) ("DNREC has set forth requirements, standards and criteria in the Technical Documents which govern its decision-making process. DNREC's actions were unlawful when it promulgated in the Technical Documents regulations which were not subject to the APA.").

   Further, "eligible expenses" is not defined under the Proposed Regulation. Again, the Proposed Regulation is insufficient in leaving the definitions to be established in an annual payer-facing notice rather than providing an opportunity for public notice and comment.

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3. **The Diagnosis Related Groups (DRG) and Ambulatory Payment Classification (APC) methodology as set forth in § 8.1 of the Proposed Regulation is not contemplated in the statute and is beyond the scope of the Department's statutory authority to establish Affordability Standards for primary care.**

   In particular, Section 8.1 of the Proposed Regulation requires the following with respect to Alternative Payment Model Adoption:

   - *8.1 By 2023, each carrier rate filing for a health benefit plan shall reflect fee schedules and reimbursement structures for inpatient and outpatient hospital facility services delivered in Delaware that are based on a fixed payment, episode-based or population-based payment methodology (e.g., not a percent of charges), including but not limited to:*
     - *DRGs for inpatient facility care; and*
     - *APCs for outpatient facility care.*

   - The Proposed Regulation defines these terms in accordance with their existing Medicare payment system framework:
     - *Ambulatory Payment Classification" or "APC" means the classification system described in 42 CFR 419.31 that is the basis of Medicare's reimbursement system for hospital outpatient services.*
     - *"Diagnosis Related Groups" or "DRGs" means the patient classification scheme set forth in 42 CFR 412.60.*

   DRGs and APCs exist in the Medicare inpatient and outpatient prospective payment system rules, and in some commercial contracts when they are negotiated between a payer and a provider for specified services. There is nothing in SS1 to SB 120 that gives the Department the authority to impose a DRG/APC methodology on health care provider contracts with insurance carriers. The terms "DRG" and "APC" do not appear in the statute. The Proposed Regulation does not address those services for which DRG and APC classifications are not available (e.g. services not provided to Medicare beneficiaries that otherwise are covered under this statutory mandate) and does not address whether specific DRG/APC structures may be negotiated in specific payer and provider contracts, consistent with present industry practices. The statutory authority to promulgate "Affordability Standards" does not extend to include blanket authority to re-write existing (and future) payer-provider contracts.[iii]

   In addition, in Section 8.2.1, 8.2.2 and 8.2.3, the Department unilaterally imposes very specific risk requirements on payers and providers, including mandating a minimum split of 30% ACO/70% carrier for Category 3A in 2023-24 (8.2.1), with escalating percentages of downside risk in subsequent years. This is beyond what the requirements of the Medicare program. The Department also appears to mirror the Medicare Shared Savings Program and/or Pathways to Success model in imposing highly restrictive limitations on risk corridors (8.2.3). The Department has not clearly articulated how its ability to define "affordability standards" and set primary care spending targets translates into statutory authority to define and write the terms of every payer and provider contract under its jurisdiction (particularly when said rate

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filing jurisdiction is limited to the subset of the commercially fully insured market, although the language in the Proposed Regulations implies otherwise).

4. **The Proposed Regulations exceed the scope and timelines that are expressly contemplated in SS 1 for SB 120.**

   The Department is surprisingly candid in documenting its intent to ignore the legislative sunset clause.[1]

   Proposed Regulation Section 9.1 notes the following:

   > *Each of the following affordability standards shall be included in every health benefit plan reimbursement structure and fee schedule implemented by every carrier in this state, and shall be unaffected by the sunset provisions of Senate Substitute 1 for Senate Bill 120 (SS1 for SB 120) of the 151st General Assembly.*

   In addition to disregarding the General Assembly's instructions and intent regarding sunset, the Department's use of "every health benefit plan reimbursement structure and fee schedule implemented by every carrier in this state" in Section 9.1 is ambiguous and concerning given the statutory limitations of the Department's authority to regulate certain types of health benefit plans. In SS 1 for SB120, the General Assembly even attempted to remind the Department of its limitations, noting: "WHEREAS, the Department of Insurance does not regulate Medicaid or employer-based plans provided under the Employee Retirement Income Security Act, or their rates." (See FN 4).

5. **The Proposed Regulations Should Be Re-Issued With Clearer Defined Terms for Key Provisions:**

   Several Defined Terms in the Proposed Regulation—including Accountable Care Organizations (ACOs), Inpatient Hospital Services and Outpatient Hospital Services —appear to mirror Medicare payment regulations, but there also seem to be inconsistencies and cross-citations to external sources (some of which were not made public in the Proposed Regulation, e.g. the Unified Rate Review Template). As currently written, the definitions in the Proposed Regulation could lead to confusion. For example, the reference to "skilled nursing" in the inpatient hospital services may be interpreted to include skilled nursing facility (nursing home) services. The Department should ensure these definitions are consistent with existing Medicare regulatory definitions, and should also clarify what standards are intended to apply when there is no equivalent Medicare definition for a specified service (i.e. NICU services, maternal/fetal medicine).

   Further, the definition of "Year" needs to be made clear and consistent throughout the regulations. Specifically, Section 10.4.3 references "the following two rate years" and Section 10.4.4.2 reference that "Fines equal to each year's value" which implies "calendar year" by definition whereas every other calculation is based on "plan year."

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If the fine is based on calendar year, the regulations should define how the calendar year fine will be calculated based on plan year data.

6. **The Enforcement Section of the Proposed Regulation, Section 10, lacks transparency and an opportunity for stakeholders to weigh in on the methods ultimately used for enforcement of the requirements set out in the Regulation.**

Section 10.1 indicates the Department shall monitor compliance through an annual review of any or all of the following:

> *10.1.1 Carrier-specific and Medicare fee-for-service data from the DHIN HCCD;*
> *10.1.2 Carrier-submitted templates that report information such as: fee-for-service payments, non-fee-for-service payments, and primary care incentive programs, requirements, numbers of participating providers, performance metrics, price, utilization and total cost trends and other information, as required in this regulation and as identified in annual notices. Carriers shall use templates supplied by the department to provide prospective and retrospective information to confirm carrier requirements were met; and*
> *10.1.3 As necessary, a market conduct exam of a carrier that may include a review of carrier contracts with healthcare providers and additional information as necessary. Any market conduct exam pursuant to this regulation shall be conducted in accordance with the provisions of 18 Del.C.§§318-321.*

This section creates uncertainty and a lack in transparency in the way the Proposed Regulation will be enforced. Under Proposed Regulation Section 10.1.1, Hospitals and health systems do not have access to the methodologies used in the Health Care Claims Database, which is an issue that we have raised previously in discussions about the Health Care Spending Benchmark, and in the Primary Care Collaborative meetingss. In addition, DHA recommends that hospitals have the opportunity to provide feedback on the carrier-submitted templates under 10.1.2. Similarly, under 10.1.3, hospitals should have the opportunity to further examine and provide feedback on the proposed "market conduct exam."

SS1 for SB 120 (along with its predecessors) established the Primary Care Collaborative to support primary care in Delaware, and to solve the problems arising from independent primary care physicians being compensated so poorly by insurers that they were left with no choice but to retire, convert to concierge practice or become employed by a large health system. The 2021 legislation (SS1), building on previous versions, added more explicit authority for the Department to establish Affordability Standards, with the expectation that the Primary Care Collaborative was charged with developing a primary care model that would meet Delaware's systemic needs.

Six months later, there is still significant work that remains on developing the primary care model, and the PCC is only beginning to convene the stakeholder meetings that are necessary

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to complete that work. Instead of completing that process and drafting regulations that synchronize the payment structure with the model, the Department has decided to re-write all existing payer and provider contracts and impose conditions that are excessive, impossible to achieve and inconsistent with the intent or express language in the statute. While we understand and appreciate the regulatory and rate filing timelines, that does not circumvent the need for an open public comment process and regulations that are within the scope of their statutory authority.

Again, thank you for the opportunity to comment on the Proposed Regulation. We request that the Proposed Regulation be withdrawn and re-proposed in line with the scope and intent of SS 1 for SB 120. We would appreciate the opportunity to work with the Department on a re-proposed regulation.

Sincerely,

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[i] "The federal government reported on January 12, 2022 that "the consumer price index, the most widely watched gauge of inflation, hit a **four-decade high of 7 percent** in December [2021] compared to the previous year." See also slide 25 from January 10th Primary Care Reform Collaborative Meeting.

[ii] Victoria Guida, *Price Spikes threaten to ground Biden's big-spending plans*, Politico, January 12, 2022, 2022-1-12 Price_spikes_threaten_to_ground_Biden_s_big-spending_plans_-_POLITICO_PRO.pdf.

[iii] In fact, the Department has previously acknowledged this limitation in response to payer comments on its Affordability Standards Report:

Affordability Standards Report: OVBHCD/DOI Comments: Delaware-Report-Public-Comments-Response-03072021.pdf

- **Highmark Delaware Comment:** Furthermore, the Report's Target for limiting of unit price growth for non-professional services will be insufficient to cover the Report's Target increase in primary care investment. In addition, annual expenditures for non-professional services are influenced by many other factors beyond unit price growth such as utilization and technology. Provider contracts are multi-year and will need to be adjusted over time. Implementing changes will require long-term planning. Like primary care, investment in these services and others also need to improve quality while controlling cost

OVBHCD Response: THE OFFICE appreciates that it does not have the authority to interfere in individual payer/provider contract negotiations. However, to the extent that THE OFFICE establishes certain requirements, THE OFFICE expects that those requirements be implemented. "No progress" will not be an acceptable outcome. Meaningful progress with measurable outcomes must be the end result under the statutory mandate of THE OFFICE.

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